



**IMACS**

International Myositis Assessment & Clinical Studies Group

# IMACS Outcomes Repository

**IMACS/JDM Working Group Meeting**

**San Diego, CA; Nov 13, 2005**

Lisa Rider, MD and Frederick Miller, MD, PhD

Environmental Autoimmunity Group,

National Institute of Environmental Health Sciences,

National Institutes of Health, DHHS

Bethesda, MD



# Outcomes Repository

- Collection of prospective clinical trials and natural history studies that are utilizing common core set measures, demographic/clinical features and outcomes
- Purpose: To prospectively validate and improve definitions of improvement and clinical trial design consensus proposals, especially for therapeutic trials, develop predictors of treatment responses
  - Allows for pooled analyses with sufficient power
  - Contributing investigators qualified for manuscripts using their data
- Restricted access to an Oracle internet database to enter core set measures, demographic, clinical features, and outcomes
  - Password protection for data entry after study approval
    - Under ACR grant, ability to support some data entry for next 1- 2 years
  - Submit study's database once completed with a codebook, description and frequency distribution of variables



# Outcomes Repository– Ethical/Regulatory Issues

- All sites must have U.S. DHHS OHSPR Federal Wide Assurance Agreement and IRBs must have DHHS approval: <http://www.hhs.gov/ohrp/>
- Possible ways to contribute to the repository include
  - PI's protocol is approved locally for IMACS data repository at NIH - local subjects will consent to the use of their data for the IMACS repository.
  - PI enrolls subjects in NIEHS IRB approved natural history protocol as a collaborating center.
  - Fully anonymous data entered after data collection - requires request for exemption to NIH Office of Human Subjects Research.
- NIH is exempt from HIPAA regulations, but local HIPAA compliance is necessary
  - Anonymized data – no date of birth, clinically sensitive data, collapse of race



# Outcomes Repository – Composition

## ● Required data:

- Core demographic, clinical features and response to therapy data
- IMACS Core Set Activity Measures: MD and Patient/Parent Global Activity, MMT24 (8 key muscles, 0 – 10 point scale preferred), (C)HAQ, Enzymes, MDAA (MyoAct, MITAX)
- Assessment of Study Outcome – Improved, Same, Worse
- Clinical Trial Design Elements

## ● Optional data:

- PRINTO/PRCSG Activity Measures: CMAS, DAS (encouraged!)
- Damage: MD and Patient/Parent Global Damage, Myositis Damage Index
- Patient-Reported Outcomes: SF-36, CHQ-PF50
- Ancillary data specific to your study: Submit as a data file to be archived in the registry



# Research Study Proposals for Repository and IMACS Group

- IMACS Outcomes Repository open to IMACS investigators for use
- IMACS members propose collaborative clinical trials, natural history studies, and other clinical investigations.
- IMACS members submit research proposal with IRB approval for study to Research Review Committee.
- Research proposals reviewed by Research Committee composed of all contributors to IMACS Outcomes Repository.



# Enter Basic Study Information to Register Your Study and Investigators

https://dir-apps.niehs.nih.gov/imacs/index.cfm?action=study.edit&studyid=1

Logout  
IMACS Membership  
Current Members  
View/Edit My Profile  
Coordinators  
**Assessment Tools**  
About the Tools  
Disease Activity Core Set Measures  
Disease Damage Core Set Measures  
Patient Reported Outcomes  
IMACS Registry Forms  
Definitions of Improvement  
**Meetings**  
About IMACS Meetings  
Meetings  
**Myositis Studies**  
Therapeutic Studies  
Natural History Studies  
**Media**  
News  
IMACS Publications  
Related Publications  
**Resources**  
Sponsors  
Sites of Interest  
**Contact Us**  
Contact IMACS  
**Data Entry**  
My Studies  
**Developer and Beta**  
Testing Links

### Study Information

**Study Number** 001

**Name of Trial** IMACS NIH Natural History Study

**Type of Trial**  
 Clinical Trial  
 Natural History Study

**Principal Investigator** Rider, Lisa

**Assessor Number** 001  
*The PI will automatically be added to the Assessor List below. You may assign a different Assessor Number if you wish.*

### Centers

001 -- Environmental Autoimmunity Group (NIH)

**Add New Center** Choose a Center if you wish to Add one

**Center Number**  
*It is recommended that you use the default value. If you have used different values in your study, please enter your values here.*

Update And Return To This Form

### Assessors

001 -- Lisa Rider  
003 -- Frederick Miller  
093 -- Michael Harris-Love  
182 -- Minal Jain  
603 -- Michelle Smith

**Add New Assessor** Choose an Assessor if you wish to add one to this study


**Assessor Number**  
*It is recommended that you use the default value. If you have used different values in your study,*



# Add Patients to Register Your Study's Patients and Assign ID Numbers

https://dir-apps.niehs.nih.gov/imacs/index.cfm?action=patient.new&studyid=1

National Institute of Environmental Health Sciences  
Division of Intramural Research

 **IMACS** International Myositis Assessment & Clinical Studies Group

[IMACS](#) >> [My Studies](#)

**General Information**

- Home
- Logout
- IMACS Membership
- Current Members
- View/Edit My Profile
- Coordinators

**Assessment Tools**

- About the Tools
- Disease Activity Core Set Measures
- Disease Damage Core Set Measures
- Patient Reported Outcomes
- IMACS Registry Forms
- Definitions of Improvement

**Meetings**

- About IMACS Meetings
- Meetings

**Myositis Studies**

- Therapeutic Studies
- Natural History Studies

**Media**

- News

**IMACS**

Patient Information

<b>Study</b>	001 -- IMACS NIH Natural History Study
<b>Patient Number</b>	<input type="text" value="035"/>
Next Sequential Number shown here. You may edit this number but it can't be a duplicate of an existing patient for this study	
<b>Patient Number Used in Study (if different from IMACS patient number)</b>	<input type="text"/>

Nov 2005

7 of 16



# Links to Add or Edit Specific Core Set Data

https://dir-apps.niehs.nih.gov/imacs/index.cfm?action=study.details&studyid=1

**IMACS** International Myositis Assessment & Clinical Studies Group

IMACS >> My Studies >> Study Details

### General Information

- Home
- Logout
- IMACS Membership
- Current Members
- View/Edit My Profile
- Coordinators

### Assessment Tools

- About the Tools
- Disease Activity Core Set Measures
- Disease Damage Core Set Measures
- Patient Reported Outcomes
- IMACS Registry Forms
- Definitions of Improvement

### Meetings

- About IMACS Meetings
- Meetings

### Myositis Studies

- Therapeutic Studies
- Natural History Studies

### Media

- News
- IMACS Publications
- Related Publications

### Resources

- Sponsors

## Study Details

You may perform the following action(s)

- Edit Basic Study Information** -- If you need to make changes to the study information, add centers, or assessors
- Add Patients** -- If you need to add a new patient
- Add/Edit Core Patient data for this Study** -- Enter Update and Certify Data for Core Patient (Form 1)
- Add/Edit MD Global Activity data for this Study** -- Enter Update and Certify Data for MD Global Activity (Form 2)
- Add/Edit Patient Global Activity data for this Study** -- Enter Update and Certify Data for Patient Global Activity (Form 3a)
- Add/Edit Parent Global Activity data for this Study** -- Enter Update and Certify Data for Parent Global Activity (Form 3b)
- Add/Edit MMT data for this Study** -- Enter Update and Certify Data for MMT (Form 4)
- Add/Edit HAQ data for this Study** -- Enter Update and Certify Data for HAQ (Form 5a)
- Add/Edit CHAQ data for this Study** -- Enter Update and Certify Data for CHAQ (Form 5b)
- Add/Edit CMAS data for this Study** -- Enter Update and Certify Data for CMAS (Form 05c)
- Add/Edit Laboratory Measures (Enzymes) data for this Study** -- Enter Update and Certify Data for Laboratory Measures (Enzymes) (Form 6)
- Add/Edit Myositis Disease Activity Assessment Tool data for this Study** -- Enter Update and Certify Data for Myositis Disease Activity Assessment Tool (Form 7)
- Add/Edit Myositis Damage Index data for this Study** -- Enter Update and Certify Data for Myositis Damage Index (Form 8)

Nov 2005



# Listing of Patients and Status of Assessments to Add/Edit Data

https://dir-apps.niehs.nih.gov/imacs/index.cfm?action=study.details&studyid=1

## Patients/Assessments

Completed Forms with an asterisk (\*) **have not been certified** by a study assessor.

### 001-002

**Assessment 1:** 06/05/2002 (First Trial Assessment)

Completed Forms	Incomplete Forms
<ul style="list-style-type: none"> <li>2 - MD Global Acitivity*</li> <li>4 - MMT</li> </ul>	<ul style="list-style-type: none"> <li>1 - Core Patient</li> <li>3a - Patient Global Activity</li> <li>3b - Parent Global Activity</li> <li>5a - HAQ</li> <li>5b - CHAQ</li> <li>05c - CMAS</li> <li>6 - Laboratory Measures (Enzymes)</li> <li>7 - Myositis Disease Activity Assessment Tool</li> <li>8 - Myositis Damage Index</li> <li>9 - MD Global Damage</li> <li>10 - Patient Global Damage</li> <li>11 - Assessment of Study Outcome</li> <li>12 - Disease Activity Score</li> </ul>

[Add Assessment for 001-002](#)

### 001-003

**Assessment 1:** 01/29/2003 (First Trial Assessment)

Completed Forms	Incomplete Forms
<ul style="list-style-type: none"> <li>4 - MMT</li> </ul>	<ul style="list-style-type: none"> <li>1 - Core Patient</li> <li>2 - MD Global Acitivity</li> <li>3a - Patient Global Activity</li> <li>3b - Parent Global Activity</li> <li>5a - HAQ</li> <li>5b - CHAQ</li> <li>05c - CMAS</li> <li>6 - Laboratory Measures (Enzymes)</li> <li>7 - Myositis Disease Activity Assessment Tool</li> <li>8 - Myositis Damage Index</li> <li>9 - MD Global Damage</li> <li>10 - Patient Global Damage</li> <li>11 - Assessment of Study Outcome</li> </ul>

# Physician Global Activity

https://dir-apps.niehs.nih.gov/imacs/index.cfm?action=mdactivityassessment.new&assessmentid=161

Go

IMACS >> My Studies >> Add New Physician Global Activity Assessment

## Add New Physician Global Activity Assessment

### Notes

Disease Activity is defined as potentially reversible pathology or physiology resulting from the myositis. Clinical findings known or suspected to be due to another disease process should not be considered in this evaluation. The global assessment of disease activity is to be judged from all the information available to you today including the subject's appearance, history, physical examination, diagnostic laboratory testing and your resultant medical therapy.

### Physician Global Activity Assessment Data

**Study Number - Patient Number** 001-003

**Assessment Number** 001 (On or near: 01/29/2003)

**IMACS Assessor** Please Select an Assessor

**Assessment Date**  
(month/date/year)

**Physician Global Activity Assessment, Visual Analog Scale**  
(0 - 10 cm)

cm Enter 1 digit after the decimal place (i.e. 5.1)

Please rate your global (overall) disease activity assessment by drawing a vertical mark on a 10-cm line according to the following scale:

- left end of line = no evidence of disease activity
- midpoint of line = moderate disease activity
- right end of line = extremely active or severe disease activity.

**Enter the measured result in the box above.**

**Also rate global disease activity on a 5-point Likert scale**

- 0 = none
- 1 = mild activity
- 2 = moderate activity
- 3 = severe activity
- 4 = extremely severe activity

**Data Entry**

Lisa Rider  
11/03/2005



# Manual Muscle Testing

## MMT 0 – 10

https://dir-apps.niehs.nih.gov/imacs/index.cfm?action=mmtscore.edit&mmtscoreid=287

### Study Data

<b>Patient Number</b>	001-005
<b>Date Certified</b>	Not certified
<b>Assessment Number</b>	1 (On or near: 06/02/2003)
<b>Assessor</b>	093 -- Harris-Love, Michael
<b>Assessment Date (month/date/year)</b>	06/02/2003
<b>Side of Body used for MMT8*</b>	<input type="radio"/> Left Side <input checked="" type="radio"/> Right Side

### Axial Muscles (0-20)

Axial	
<b>Neck Flexors**</b>	<input type="radio"/> 0 <input type="radio"/> Trace <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input checked="" type="radio"/> 6 <input type="radio"/> 7 <input type="radio"/> 8 <input type="radio"/> 9 <input type="radio"/> 10 <input type="radio"/> Not Assessed
<b>Neck Extensors</b>	<input type="radio"/> 0 <input type="radio"/> Trace <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6 <input type="radio"/> 7 <input type="radio"/> 8 <input type="radio"/> 9 <input checked="" type="radio"/> 10 <input type="radio"/> Not Assessed
<b>Axial Muscles (0-20)</b>	16 / 20

### Proximal Muscles (0-160)

	Right											Left										
<b>Trapezius</b>	<input type="radio"/> 0 <input type="radio"/> Trace <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6 <input type="radio"/> 7 <input type="radio"/> 8 <input type="radio"/> 9 <input checked="" type="radio"/> 10 <input type="radio"/> Not Assessed	<input type="radio"/> 0 <input type="radio"/> Trace <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6 <input type="radio"/> 7 <input type="radio"/> 8 <input type="radio"/> 9 <input checked="" type="radio"/> 10 <input type="radio"/> Not Assessed																				
<b>Deltoid middle**</b>	<input type="radio"/> 0 <input type="radio"/> Trace <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6 <input type="radio"/> 7 <input type="radio"/> 8 <input checked="" type="radio"/> 9 <input type="radio"/> 10 <input type="radio"/> Not Assessed	<input type="radio"/> 0 <input type="radio"/> Trace <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6 <input type="radio"/> 7 <input type="radio"/> 8 <input type="radio"/> 9 <input checked="" type="radio"/> 10 <input type="radio"/> Not Assessed																				
<b>Biceps brachii**</b>	<input type="radio"/> 0 <input type="radio"/> Trace <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6 <input type="radio"/> 7 <input type="radio"/> 8 <input checked="" type="radio"/> 9 <input type="radio"/> 10 <input type="radio"/> Not Assessed	<input type="radio"/> 0 <input type="radio"/> Trace <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6 <input type="radio"/> 7 <input type="radio"/> 8 <input type="radio"/> 9 <input checked="" type="radio"/> 10 <input type="radio"/> Not Assessed																				

# Laboratory – Enzymes, Cr

https://dir-apps.niehs.nih.gov/imacs/index.cfm?action=labresult.new&assessmentid=184

Go

## Serum Levels Data

**Study Number - Patient Number** 001-002

**Assessment Number** 001 (On or near: 06/05/2002)

**Assessor** Please Select an Assessor

**Assessment Date**  
(month/date/year)

**Creatine Kinase (CK)**  
(IU/L)

Result

Upper Limit of Normal

**Adolase**  
(IU/L)   
Enter 1 digit after the decimal (i.e.  
7.6) Result

Upper Limit of Normal

**Aspartate amino Transferase**  
(AST) or Serum Glutamic  
Oxalacetic Transaminase (SGOT)  
(IU/L)

Result

Upper Limit of Normal

**Alanine Amino Transferase (ALT)**  
or Serum Glutamic Pyruvic  
Transaminase (SGPT)  
(IU/L)

Result

Upper Limit of Normal

**Lactate dehydrogenase (LDH)**  
(IU/L)

# Options to Edit or Certify Data Once Entered

https://dir-apps.niehs.nih.gov/imacs/index.cfm?action=mdactivityassessment.details&mdactivityassessmentid=2

- General Information**
- Home
- Logout
- IMACS Membership
- Current Members
- View/Edit My Profile
- Coordinators
- Assessment Tools**
- About the Tools
- Disease Activity Core Set Measures
- Disease Damage Core Set Measures
- Patient Reported Outcomes
- IMACS Registry Forms
- Definitions of Improvement
- Meetings**
- About IMACS Meetings
- Meetings
- Myositis Studies**
- Therapeutic Studies
- Natural History Studies
- Media**
- News
- IMACS Publications
- Related Publications
- Resources**
- Sponsors
- Sites of Interest
- Contact Us**
- Contact IMACS
- Data Entry**

## IMACS

You may perform the following action(s)

- Edit This Score** -- Edit the data in a Physician Global Activity Assessment record
- Certify This Score** -- Certify the data is complete and should not be further edited.
- Add/Edit/Certify/View Other Physician Global Activity Assessment Scores** -- View (and possibly edit) data for other subjects in this study.
- Go to Study 001** -- Edit/View summary data of study. Enter data for study.

**Notes**

Disease Activity is defined as potentially reversible pathology or physiology resulting from the myositis. Clinical findings known or suspected to be due to another disease process should not be considered in this evaluation. The global assessment of disease activity is to be judged from all the information available to you today including the subject's appearance, history, physical examination, diagnostic laboratory testing and your resultant medical therapy.

**Physician Global Activity Assessment Data**

<b>Study Number - Patient Number</b>	001-002
<b>Assessment Number</b>	001 (On or near: 06/05/2002)
<b>IMACS Assessor</b>	001 -- Lisa Rider
<b>Assessment Date (month/date/year)</b>	10/24/2005
<b>Physician Global Activity Assessment, Visual Analog Scale (0 - 10 cm)</b>	9.1
<b>Also rate global disease activity on a 5-point Likert scale</b>	3 = severe activity
<b>Data Entry</b>	Lisa Rider 10/31/2005

# Certifying Data Locks and Finalizes It

https://dir-apps.niehs.nih.gov/imacs/index.cfm?action=mdactivityassessment.certify&mdactivityassessmentid=2

IMACS >> My Studies

**General Information**

- Home
- Logout
- IMACS Membership
- Current Members
- View/Edit My Profile
- Coordinators

**Assessment Tools**

- About the Tools
- Disease Activity Core Set Measures
- Disease Damage Core Set Measures
- Patient Reported Outcomes
- IMACS Registry Forms
- Definitions of Improvement

**Meetings**

- About IMACS Meetings
- Meetings

**Myositis Studies**

- Therapeutic Studies
- Natural History Studies

**Media**

- News
- IMACS Publications
- Related Publications

**Resources**

- Sponsors
- Sites of Interest

**IMACS**

Please review the data below. By clicking this button you are certifying that the data is correct and you will not be able to edit it further.

I certify that this data is correct

**Notes**

Disease Activity is defined as potentially reversible pathology or physiology resulting from the myositis. Clinical findings known or suspected to be due to another disease process should not be considered in this evaluation. The global assessment of disease activity is to be judged from all the information available to you today including the subject's appearance, history, physical examination, diagnostic laboratory testing and your resultant medical therapy.

**Physician Global Activity Assessment Data**

<b>Study Number - Patient Number</b>	001-002
<b>Assessment Number</b>	001 (On or near: 06/05/2002)
<b>IMACS Assessor</b>	001 -- Lisa Rider
<b>Assessment Date (month/date/year)</b>	10/24/2005
<b>Physician Global Activity Assessment, Visual Analog Scale (0 - 10 cm)</b>	9.1
<b>Also rate global disease activity on a 5-point Likert scale</b>	3 = severe activity
<b>Data Entry</b>	Lisa Rider 10/31/2005



# Summary

- IMACS Outcomes Repository is being developed with support of the ACR to validate definitions of improvement, clinical trial design issues and develop predictors of treatment responses
  - All IMACS members are encouraged to submit data from their own trials and studies to the repository
  - Regulatory requirements- local IRB approval or exemption (retrospective), register with DHHS
  - IMACS core set measures and other information needed from a number of clinical studies
- Repository and IMACS Group open for research proposals, following review by the research committee



# Acknowledgements – Sponsors



National Institute of Environmental Health Sciences



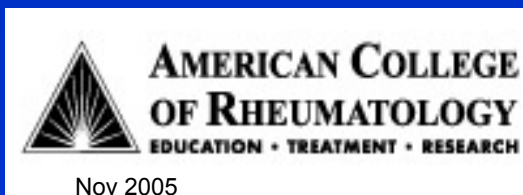
National Institute of Arthritis and Musculoskeletal and Skin Diseases



The NIH Office of Rare Diseases



The Myositis Association



American College of Rheumatology